

10080832

**510(k) Summary**  
**Sorin Group Deutschland GmbH**  
**Stöckert S5 System Gas Blender**  
*(per 21 CFR 807.92)*

**JUL 30 2008**

**1. SPONSOR**

Sorin Group Deutschland GmbH  
Lindberghstrasse 25  
80939 Munich  
Germany

Contact Person: Helmut Höfl  
Telephone: 011 49 89 323 010

Date Prepared: May 14, 2008

**2. DEVICE NAME**

Proprietary Names: Stöckert S5 System  
Common/Usual Names: Heart Lung Machine  
Classification Names: Cardiopulmonary bypass heart lung machine console and accessories  
Proprietary Name: Stöckert S5 System

**3. PREDICATE DEVICES**

Stöckert S5 System (Parent Device)  
Terumo® Advanced Perfusion System 1, K022947

**4. DEVICE DESCRIPTION**

The Stöckert Gas Blender is an optional accessory to and designed to be operated with the Stöckert S5 System. It cannot be operated independently from the heart lung machine console.

**5. INTENDED USE**

The modified Stöckert S5 System is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.

## **6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE**

Sorin Group Deutschland GmbH bases the claim of substantial equivalence of the Stöckert Gas Blender to the cited predicate devices based on equivalence in intended use, fundamental technological and operational characteristics. Information and testing submitted in this Special 510(k): Device Modification demonstrates that the Stöckert Gas Blender integrated with the S5 System Stöckert Gas Blender with the S5 System do not raise new issues of safety or effectiveness.

## **7. PERFORMANCE INFORMATION**

Design verification and validation information provided in this Special 510(k): Device Modification demonstrates that the product meets prospectively defined design and performance specifications.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 30 2008

Sorin Group Deutschland  
c/o Ms. Rosina Robinson, RN, Med, RAC  
Principal Consultant  
Medical Device Consultants, Inc.  
49 Plain Street  
North Attleboro, MA 02760

Re: K080832  
Stockert S5 System  
Regulation Number: 21 CFR 870.4220  
Regulation Name: Cardiopulmonary Bypass Heart-Lung Machine Console  
Regulatory Class: Class II (two)  
Product Code: DTQ, DWB, DTR, KRI, DTW, DXS, DWA, KRL, DTX  
Dated: June 13, 2008  
Received: June 19, 2008

Dear Ms. Robinson:


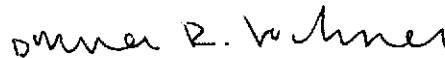
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K080832

Device Name: Stöckert S5 System

Indications for Use:

The modified Stöckert S5 System is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachner  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K080832